

REMARKS and ARGUMENTS

This amendment and request for continued examination is being submitted on August 28, 2003. A Final Rejection was mailed on 02/28/2003. A response was originally due on 5/28/2003. Filed herewith is a Request for Continued Examination and a request for 3-month extension of time and appropriate fees; thus a response is due on August 28, 2003. Accordingly, this amendment and RCE are timely filed. Applicants respectfully request the amendment and arguments submitted herewith be made of record in the instant application.

Claim Status

Claims 1, 3, 5, 8-12, 20-30 are pending.

Claims 2, 4, 6, 7 and 13-19 have been cancelled by amendment filed herewith.

Claim 1 has been amended to recite that the glass composition may or may not contain HA particles. Support for this amendment is found in the provisional application as filed at page 18, col. 1, last paragraph.

Claim 1 and 20 have been amended to recite that the amount of HA be "up to 50 wt %". Support for this amendment is found in the provisional application as filed at page 11, col. 1, lines 11-12, page 12, lines 11-13 and at page 18, col. 1, last paragraph.

Claims 5, 29 and 30 have been amended or added to reflect that the layers are graded in either or both of the silica and/or HA content. Support for this amendment is found in the specification as filed and in the provisional application at page 26, lines 3-4, and at page 7, col. 1, lines 24-25 and page 7, col. 2, lines 7-8.

Claims 8-10 have been amended to change their dependency.

Claim 11 has been amended so it conforms to other claims.

Claim 12 has been amended to delete a concentration range.

Support for newly added claims 21 and 23 is found in the provisional application as filed at page 16, lines 7-8 of paragraph no. 1.

Support for newly added claims 22, 24, 26 and 28 is found throughout the provisional specification and instant specification as filed everywhere there is disclosed dual layers.

Support for newly added claims 25 and 27 is found in the provisional application as filed at page 10, column 2, 5th and 6th lines from the bottom.

No new matter is added by these amendments, and entry is respectfully requested.

Applicant initiated interview

Applicants gratefully acknowledge the telephone interview on July 16, 2003 between Supervisory Patent Examiner Jones and Examiner Sperty.

CLAIM REJECTIONS

Priority

The Office Action (paper no. 11, mailed 2/28/2003, paragraph no. 1, denies Applicant's claim for priority to Provisional Application 60/201,556, because allegedly "the provisional application does not provide a specification disclosing the claimed invention, therefore there is no support for the claimed invention." In the telephonic interview conducted between Supervisory Patent Examiner Jones and Charles R. Nold on July 16, 2003, SPE Jones alleged that the provisional application 60/201,556 only had support for the recitation of a glass/Hydroxyapatite mixture of 50/50 weight percent.

Further, SPE Jones alleged that the provisional application only had support for the glass/hydroxyapatite layer being the outer layer. No other objections to the specification have been made. Applicants respectfully disagree for the reasons set forth below.

The standard for a provisional patent application can be found in MPEP 601 which states that 35 U.S.C. 111(b) mandates the contents of a provisional application specification. 35 U.S.C. 111(b) mandates that a provisional application shall comply with the first paragraph of 35 U.S.C. 112 and include a drawing if necessary. A claim is not required. Applicants respectfully assert that the provisional application as filed does provide support for the invention as currently claimed. The Specification is a compilation of six different peer-reviewed publications authored in some instances by inventors of the instant.

Restated, the issue is whether the instant claims complies with 35 U.S.C. 112, first paragraph, i.e. is the invention claimed in the instant invention described and enabled in the specification. Applicants respectfully assert that it is. It was alleged that the provisional application only had support for the recitation of a glass/Hydroxyapatite mixture of 50/50 weight percent. Applicants respectfully disagree. Applicants assert that there is broad support in the provisional application for the range claimed, which is "up to 50 wt %". Support for the claimed range of glass/hydroxyapatite is found in the provisional application as follows:

1. page 11, col. 1, lines 11-12: "It was possible to fabricate coatings whose external layer had silica contents as low as 53 wt% **or were a mixture of HA particles and glass.** (emphasis added) (note: no mention of the amount of HA, thus an open range)

2. page 12, lines 11-13: "Hydroxyapatite (HA) particles were mixed with the glass powder and the mixture was placed on the outer surface of the coatings to render them more bioactive." (note: no mention of the amount of HA, thus an open range)
3. page 18, col. 1, last paragraph: "The glasses can be used alone or mixed with HA." (note: no mention of the amount of HA)

As the Examiner is of course aware, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). Precisely how close the original description must come to comply with the description requirement of 35 U.S.C. § 112 must be determined on a case-by-case basis. *In re Wilder*, 736 F.2d 1366, 1375, 222 USPQ 369, 372 (Fed. Cir. 1984). There is no per se rule that ranges in claims added in a continuation application must correspond exactly with those disclosed in the parent application. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F. 2d 1570, 227 USPQ 177 (Fed. Cir. 1985). Accordingly, under *Ralston* it is Applicant's position that the repeated mention in the specification of using a mixture of HA and glass, coupled with a specific example showing a glass/HA ratio of 50/50 is sufficient disclosure to enable and describe the current invention as claimed. Under *In re Kaslow*, the provisional supports the Utility application because it would have been clear to the artisan, upon reading the provisional, that a wide range of HA/glass mixtures are part of the instant invention. This is because the provisional recites, at least in three places as

mentioned above, the use of *some quantity* of HA particles in the glass/HA mixture, and also provides a mid-point range of 50/50.

During the interview between SPE Jones and Charles Nold it was also alleged that the provisional application for which priority is sought only discloses and enables a multilayer article for which the HA is located **only** in the outermost layer. Applicants respectfully disagree with this position. Support for incorporating HA into the layers as claimed is found in the provisional application as filed as follows: page 2, col. 2, lines 32-34 which recite: "Layered glass coatings with embedded HA particles (<20µm) were also fabricated; in these coatings the final layer was a composite of glass and HA (50/50 wt%)." (note that the provisional recites "layered glass *coatings*, (emphasis added) with embedded HA particles. This means more than one coating, which would inherently mean other than just the outermost coating. Thus Applicants respectfully assert that there is indeed support for the claimed invention in the provisional, and withdraw of the objection is respectfully requested.

Claim Rejections- 35 USC § 102

Claims 1-19 have been rejected under 35U.S.C. 102(b) as allegedly being unpatentable over Bioceramics: Materials and Applications article titled "Glass-Hydroxyapatite coatings on titanium-based implants" allegedly published in December 1999.

Applicants respectfully traverse this rejection. The publication referred to in the Office Action was actually published on 2/23/2002, thus it is not prior art under 35 U.S.C. 102(b). Evidence of this publication is was previously submitted and made of

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record, and it is a letter from the Publisher, The American Ceramic Society. The letter states that "the first books being mailed to customers on 2/23/2000."

Withdrawal of the rejection is respectfully requested.

Claim Rejections- 35 USC § 103


Claim 20 has been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bioceramics: Materials and Applications article titled "Glass-Hydroxyapatite coatings on titanium-based implants" allegedly published in December 1999. Applicants respectfully traverse this rejection. As, explained above, the reference is not anticipatory under 35 U.S.C. 102(b), and therefore this rejection must fail.

Conclusion

Having overcome all rejections, Applicants respectfully requests that a timely Notice of Allowance be issued in this application. If a telephone conversation will expedite the prosecution of this application, the Examiner is kindly invited to call Applicant's representative at the telephone number listed below.

All fees believed due have been submitted. If Applicant is wrong in this assumption, the PTO is authorized to charge any deficiency to Applicant's deposit account number 120690. The PTO is not authorized to charge the issue fee to this account.

Respectfully Submitted,


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